U.S. Department of Veterans Affairs

Office of Research and Development

Pain Opioid Actively Managed Portfolio (POp AMP)

Request for Applications Summer 2023

April 18, 2023

POP AMP FEATURES

Pain Opioid AMP

Rotational leadership model

Proactively interact with relevant VA clinical/operations and NIH/DoD/other funder contacts

Ensure that ORD is not funding the same work as clinical/operations partners

Proactive management of the portfolio community, including bringing together researchers and/or other stakeholders to accomplish goals

The ability to stand up agile funding mechanisms when required

POP AMP BROAD RFAS

- **Companion Pre-Application (I02)**
- **Parent RFA**
  - **Pre-clinical, observational and epidemiological studies**
- **Clinical Trial RFA**
  - **Single and Multi-site Clinical Trials**

POP AMP PURVIEW

1. Clinical studies of the genetic, anatomical, and behavioral basis of algesia (pain), or tolerance, addiction, opioid metabolism, and tapering of opioid medication in acute and chronic painful conditions.
2. Clinical treatments emphasizing non-opioid medications and complementary and integrative approaches.
3. Implementation of treatments and approaches across VAMCs, evaluation of methods to enhance pain services, and evaluation of the quality and safety of pain care.
4. Preclinical development and translation of non-opioid therapies; and the accompanying anatomical, molecular, biochemical, behavioral, and genetic mechanism(s).

POP AMP PURVIEW

5. Studies identifying therapeutic targets for algesia (pain), tolerance and/or addiction to opioid medication in acute and chronic painful conditions.
6. Interventional and observational research of interventions to improve outcomes in opioid use disorder, including new models for OUD care, medication and behavioral therapy for OUD, use of overdose rescue medication.
7. Examination of pharmacology, pharmacotherapeutics, pharmacogenomics, and phenotype as well as the use of functional outcomes (e.g., correlating subjective pain measures with objective measures of function such as ADL, gait kinetics and kinematics, range of motion, and QoL or activity measures, etc.).

ELIGIBILITY-PI & MEDICAL CENTER

- PI must have a MD, PhD, or equivalent doctoral degree in a medical, biological, or behavioral science field.
- PI must have a VA paid appointment of at least 25 hours/week (5/8th FTE) in place before funding can begin
- Directors letter must confirm a commitment for a 5/8 appointment if funded.
  - Investigators with less than a 5/8th VA paid appointment must obtain approval of a waiver of the 5/8th FTE eligibility requirement for inclusion with their application for funding.
- All VA medical centers with an active research program are eligible.
- Each VA medical center must be registered as an applicant organization in Grants.gov and eRA Commons before any proposals can be submitted.

ELIGIBILITY-CO-I & BUDGET

- A Site PI must meet the same qualifications as a PI and be registered in ePromise at their current site.
- Non-VA investigators who have an MD/PhD equivalent are eligible to serve in the role of Co-investigator
- They cannot be listed as such on the budget forms. The Co-investigator role may be described in the proposal narrative and in the written budget justification.
- On the budget forms they should be reflected as a consultant or as having an Intergovernmental Personnel Act (IPA) assignment, if appropriate.
- If providing research services to the VA through a contract, the cost of the contract should be included on the budget forms under “All Other” expenses.
- Non-U.S. collaborators may only serve as unpaid consultants.

WAIVERS

- **Non-Veteran Enrollment Waiver**
  - **see VHA Directive 1200.01**
- **Eligibility Waiver see: Program Guide 1200.15**
- **Off Site Waiver see: Program Guide 1200.16**

Waivers are project specific.

- **Waiver Categories:**
  - **Offsite Research**
  - **Exceeding Duration or Budget Cap**
  - **Inclusion of Videos,**
  - **PI Eligibility,**
  - **Resubmissions**
  - **IPAs Make up a Large Percentage of Budget**
- **Deadline: May 1, 2023 (see RFAs)**

WAIVERS

- Copy of waiver approval letters must be included in the "Letters of Support" section of the application.

- Missing letters are considered fatal errors.

- Recruitment of Non-Veterans:

  Approved Enrollment of non-Veterans in ORD funded research required for all projects with non-Veterans (including VA employees) if awarded

REQUIREMENTS

MANDATORY REQUIREMENT:

Completion of the Involved Personnel and Collaborators information.

- **A List of ALL named personnel and collaborators with their VA and non-VA institutions, city, and state must be included in the letters of support section.**

This includes: ***PD/PI(s), co-investigators***
personnel with ANY role in the study
IPAs, consultants
mentors, collaborators,
advisory panel members, letter writers,
active partners (Program offices).

Note: If only named in the bibliography or Biographical Sketch section, they do not need to be included.

REQUIREMENTS

MANDATORY REQUIREMENT:

Completed for each Involved Personnel/Collaborator/Named person:

- **Name (Last, First)**
- **Degree**
- **Project Role**
- **VA Medical Center, City, State or VA CBOC, City, State (as applicable) (NOTE: listing just VHA is not sufficient)**
- **Academic Institution(s) or Non-VA Organization Name(s), City, State (as applicable)**

- **If individual has a joint VA and academic appointment, both must be listed**

REQUIREMENTS

MANDATORY REQUIREMENT:

A table of contents for the letters of support that lists each letter writer's

- **Name**
- **Position**
- **Office/institution**

- **Director's Letter must include language supporting protected time for clinician researchers**

PARENT & CLINICAL TRIAL RFAS

- Research Plan
  - Background and Significance
  - Preliminary Studies
  - Research Design and Methods
  - Implementation and Dissemination if HSRD
- Progress Report (not required for HSRD)
- Human Subjects
- Vertebrate Animals
- Multiple PI Leadership Plan
- Letters of Support
- Appendix
  - Appendix 1 Abbreviations
  - Appendix 2 Enrollment/Recruitment Table
  - Appendix 3 Recruitment and Retention Plan
  - Appendix 4 Multi-site Management Plan
  - Appendix 5 Milestones and Timeline
  - Appendix 6 Veteran Engagement Plan

PARENT MERIT REVIEW AWARD

PD/PIs may request funding for a maximum of four (4) years, based on the total project maximum amount outlined below.

There is no annual budget cap; thus, variable funding may be utilized as long as the overall budget cap (based on years requested) is maintained.

The salary for all personnel, including the contact PD/PI is included in this cap.

1 year = $300,000 max
2 years = $600,000 max
3 years = $900,000 max
4 years = $1,200,000 max

Clinical Trial Award Budget Cap and Duration

Budget Item	Limit for Single Site	Limit for Multi-VAMC Sites
Budget Cap	• For two (2) years, $600,000 • For three (3) years, $900,000 • For four (4) years, $1,200,000	For a 2-site a total: • For two (2) years, $600,000 • For three (3) years, $1,125,000 • For four (4) or five (5) years, $1,500,000 • Additional $100,000 per site per year for each additional site.
Duration	Up to four (4) years	Up to five (5) years

QUESTIONS

RFAs:

http://vaww.research.va.gov/funding/rfa.cfm